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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,481	01/08/2001	Mark Marchionni	47506 (47843)	4213

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1647	17

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,481	MARCHIONNI ET AL.	
	Examiner	Art Unit	
	Stephen Gucker, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-4, 26-34, and 41** (each in part), drawn to a method of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

II. Claims **1-4 and 35-41** (each in part), drawn to a method of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

III. Claims **5-7, 26-34, and 41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

IV. Claims **5-7 and 35-41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

V. Claims **8-10, 26-34, and 41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

VI. Claims **8-10 and 35-41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

VII. Claims **11-13, 26-34, and 41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma* comprising administering a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

VIII. Claims **11-13 and 35-41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

IX. Claims **14-16, 26-34, and 41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a

therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

X. Claims **14-16 and 35-41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

XI. Claims **17-19, 26-34, and 41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

XII. Claims **17-19 and 35-41** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

XIII. Claims **20, 21, 26-34, and 41** (each in part), drawn to a method of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

XIV. Claims **20, 21, and 35-41** (each in part), drawn to a method of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal

suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

XV. Claims **22-34 and 41** (each in part), drawn to a method of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1**, classified in class 514, subclass 2, for example.

XVI. Claims **22-25 and 35-41** (each in part), drawn to a method of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1**, classified in class 514, subclass 44, for example.

XVII. Claims **42-45, 68-76, and 80-82** (each in part), drawn to a method of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XVIII. Claims **42-45 and 77-82** (each in part), drawn to a method of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XIX. Claims **46-48, 68-76, and 80-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XX. Claims **46-48 and 79-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXI. Claims **49-51, 68-76, and 80-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XXII. Claims **49-51 and 79-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXIII. Claims **52-54, 68-76, and 80-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma* comprising administering a therapeutically effective amount

of **GDF-1 and neurotrophin-3 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 2, for example.

XXIV. Claims **52-54 and 79-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXV. Claims **55-57, 68-76, and 80-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XXVI. Claims **55-57 and 79-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXVII. Claims **58-60, 68-76, and 80-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of

GDF-1 and neurotrophin-3, classified in class 514, subclass 2, for example.

XXVIII. Claims **58-60 and 79-82** (each in part), drawn to a method of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXIX. Claims **61, 62, 68-76, and 80-82** (each in part), drawn to a method of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XXX. Claims **61, 62, and 79-82** (each in part), drawn to a method of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

XXXI. Claims **63-76 and 80-82** (each in part), drawn to a method of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective

amount of **GDF-1 and neurotrophin-3**, classified in class 514, subclass 2, for example.

XXXII. Claims **63-67 and 79-82** (each in part), drawn to a method of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, classified in class 514, subclass 44, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-XXXII are directed to methods that are distinct both physically and functionally, and are not required one for the other.

4. Invention I requires search and consideration of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention II requires search and consideration of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

5. Invention III requires search and consideration of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention IV requires search and consideration of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

6. Invention V requires search and consideration of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention VI requires search and consideration of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

7. Invention VII requires search and consideration of treating a mammal suffering from or susceptible to decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma comprising administering a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention VIII requires search and consideration of treating a mammal suffering from or susceptible to decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

8. Invention IX requires search and consideration of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention X requires search and consideration of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

9. Invention XI requires search and consideration of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention XII requires search and consideration of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

10. Invention XIII requires search and consideration of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention XIV requires search and consideration of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

11. Invention XV requires search and consideration of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a

therapeutically effective amount of **GDF-1**, which is not required by any of the other Inventions. Invention XVI requires search and consideration of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1**, which is not required by any of the other Inventions.

12. Invention XVII requires search and consideration of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XVIII requires search and consideration of *treating or preventing nerve cell death or degeneration* comprising administering to a mammal suffering from or susceptible to nerve cell death or degeneration a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

13. Invention XIX requires search and consideration of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XX requires search and consideration of treating a mammal suffering from or susceptible to *stroke or heart attack* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

14. Invention XXI requires search and consideration of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a

therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XXII requires search and consideration of treating a mammal suffering from or susceptible to *brain or spinal cord trauma or ischemia* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

15. Invention XXIII requires search and consideration of a method of treating a mammal suffering from or susceptible to decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions. Invention XXIV requires search and consideration of treating a mammal suffering from or susceptible to decreased blood flow or nutrient supply to retinal tissue or optic nerve, or retinal ischemia or trauma, or optic nerve injury, or glaucoma comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

16. Invention XXV requires search and consideration of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XXVI requires search and consideration of treating a mammal suffering from or susceptible to *post-surgical neurological deficits or neurological deficits associated with cardiac arrest* comprising

administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

17. Invention XXVII requires search and consideration of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XXVIII requires search and consideration of treating a mammal suffering from or susceptible to *peripheral nerve damage* comprising administering a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

18. Invention XXIX requires search and consideration of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XXX requires search and consideration of treating a *neurodegenerative disease or neuropathy* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

19. Invention XXXI requires search and consideration of a method of *improving functional capability of a mammal* comprising administering to a mammal suffering from or susceptible to said disease a therapeutically effective amount of **GDF-1 and neurotrophin-3**, which is not required by any of the other Inventions. Invention XXXII requires search and consideration of a method of *improving functional capability of a mammal* comprising administering to a mammal

suffering from or susceptible to said disease a therapeutically effective amount of a **nucleic acid encoding GDF-1 and a nucleic acid encoding neurotrophin-3**, which is not required by any of the other Inventions.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

21. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Stephen Gucker, Ph.D.** whose telephone number is 703-308-6571. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
July 1, 2003

Gary L. Kunz
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